

OFFICE OF SPECIAL MASTERS

No. 05-394V

August 11, 2006

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EDWINA BENGTON, Parent of \*  
BRIAN BENGTON, a Minor, \*

Petitioner, \*

v. \*

SECRETARY OF THE DEPARTMENT OF \*  
HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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Hepatitis B vaccine followed  
almost five weeks later by ADEM;  
is that too long for causation?

**ORDER TO SHOW CAUSE<sup>1</sup>**

Petitioner filed a petition dated March 23, 2005, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., and an amended petition dated June 24, 2005, on behalf of her son Brian Bengton (hereinafter, “Brian”), alleging that hepatitis B vaccine administered

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<sup>1</sup> Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document’s disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

on May 20, 2002, caused Brian a neurological demyelinating disorder, later diagnosed as acute disseminated encephalomyelitis (ADEM) and, sometimes, as multiple sclerosis (MS)..

Petitioner is ORDERED TO SHOW CAUSE by September 29, 2006 why this case should not be dismissed.

### **FACTS**

Brian was born on February 12, 1990. On July 20, 1999, he received his first hepatitis B vaccination. Med. recs. at Ex. 1, p. 2. On May 20, 2002, he received another hepatitis B vaccination. Med. recs. at Ex. 1, p. 5.

On July 2, 2002, Brian had a head CT scan because of abnormal balance and incoordination. Med. recs. at Ex. 1, p. 9. Dr. T.J. Koelz concluded it was essentially normal. Brian had a prominent cisterna magna. Dr. Koelz recommended an MRI to assess further his posterior fossa. *Id.*

On July 2, 2002, Brian had a brain MRI. Med. recs. at Ex. 12, p. 271. There were multiple foci of abnormal high signal on T2 and FLAIR weighted sequences scattered throughout the white matter of both cerebral hemispheres, including the major and minor forceps and the corpus callosum as well as additional foci of abnormal signal present within the white matter of the right cerebellar hemisphere, the medulla on the left, and the midline of the pons. All these areas of signal abnormality demonstrated low attenuation on T1 weighted images as well as normal to slightly increased signal on diffusion weighted sequences. After gadolinium, many of these lesions demonstrated abnormal enhancement centrally within most if not all these lesions, but the overall extent of enhancement was less than the signal abnormality present on T2 and FLAIR weighted sequences. In addition, two or three of these lesions might demonstrate some

central low attenuation within the enhanced region but no definite pattern of ring enhancement. There were no findings of extra-axial hemorrhage or midline shift, obliteration of basal cisterns or other regions of abnormal enhancement noted throughout the posterior fossa, cerebral hemispheres. He had a prominent cisterna magna. Differential would include ADEM , vasculitis, as well as MS. Med. recs. at Ex. 12, pp. 271-72. The MRI of Brian's cervical spine showed foci of abnormal signal enhancement within the pons and the medulla of the brain stem, but the cervical cord was normal. Med. recs. at Ex. 12, p. 272.

On July 2, 2002, Brian was admitted to Children's Hospitals and Clinics because of an acute onset of stumbling, slurred speech, an MRI showing multifocal white matter disease, and a preliminary diagnosis of an allergic disseminated encephalomyelitis, according to Dr. Stephen C. Marker. Med. recs. at Ex. 1, p. 11. Brian was essentially up until noon the day of admission when his father noted stumbling, slurred speech, and falling when walking. On further questioning, 10 days previously, Brian was playing catch and was not playing well. (That would put onset at June 23, 2002, 34 days post-vaccination or almost five weeks.) During the past week, he had some slurring of his speech and increased laughing with some emotional lability that might not have been normal. He had no illnesses recently. On examination, he had some ataxia and gait disturbance. Dr. Marker's impression was allergic disseminated encephalomyelitis. *Id.*

On July 8, 2002, Brian had a follow-up head MRI. Med. recs. at Ex. 12, p. 277. As on the last MRI, there were numerous lesions of various size scattered throughout cerebral white matter bilaterally. The most conspicuous lesion was in peritriangular white matter and in the centrum semiovale on each side. Many of the lesions were slightly larger in overall volume but the

margins of several lesions were somewhat less distinct. Additional similar-appearing lesions were seen within the corpus callosum, along the posterior limb of each internal capsule, in the right cerebellar white matter, and in the anterior midline of both pons and medulla. The lesions continued to demonstrate T1 and T2 prolongation. The distribution of lesions was almost identical to that of the prior MRI. Currently, there was no evidence of abnormal enhancement in any lesion unlike the last MRI where virtually all lesions had contrast enhancement. No new lesions were seen. *Id.*

On July 30, 2002, Brian saw Dr. Lawrence Burstein, a neurologist. Med. recs. at Ex. 3, p. 70. His mother related that there had been concerns in the past about possible Asperger syndrome (autism). *Id.*

On August 20, 2002, Brian had a head MRI. Med. recs. at Ex. 3, p. 62. Since the July 2, 2002 MRI, there had been reduction in size and enhancement of a subset of white matter lesions. However, there had also been development of new lesions. The waxing and waning course of white matter lesions within the cerebral hemispheric white matter was atypical for ADEM, but still most consistent with that diagnosis. *Id.*

On November 11, 2002, Brian's mother gave a full history to Dr. Burstein. Med. recs. at Ex. 3, p. 133. Brian had no reaction to the vaccine and did well until approximately the end of June when he had a relatively sudden onset of tingling and funny sensations bilaterally in his hands. He had difficulty throwing things and then acted as if he were drunk and would lose his balance. He saw his local physician on July 2, 2002 and had an MRI which showed numerous enhancing lesions in his brain and brain stem. *Id.*

On July 18, 2003, Brian had a head MRI which showed no change since the MRI of June 20, 2003. Med. recs. at Ex. 3, p. 13.

On October 9, 2003, Dr. Ralph Shapiro, an immunologist, saw Brian for recurrent demyelinating encephalopathic process/probable multiple sclerosis (MS). Med. recs. at Ex. 1, p. 12. Brian was vastly improved on Copaxone. *Id.*

On October 28, 2003, Brian had a head MRI. Med. recs. at Ex. 3, p. 4. The findings were compatible with ADEM. There was no change compared to the July 15, 2003 MRI. There was no acute demyelinating process. *Id.*

### **DISCUSSION**

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical

communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, Brian would not have had ADEM, but also that the vaccine was a substantial factor in bringing about his ADEM. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In the hepatitis B vaccine-demyelinating disease Omnibus proceeding, the undersigned ruled that hepatitis B vaccine could cause GBS, CIDP, TM, and MS. ADEM was not an issue in the four paradigm cases. The undersigned is aware that Dr. Burstein considers Brian to have MS. The undersigned is not sure why. Although there were some changes in Brian's brain lesions initially, eventually Brian's brain MRIs stabilized. He never had lesions in his spinal cord.

An another ADEM case that petitioner's counsel handled, Tufo v. Secretary of HHS, No. 98-108V, 2001 WL 286911 (Fed. Cl. Spec. Mstr. Mar. 2, 2001), Jerry Tufo's ADEM (or TM, there was some debate over which he had) occurred 18 days post-MMR. Here, Brian's ADEM occurred 34 days after vaccination, according to petitioner's detailed history that she gave separately to Dr. Marker and to Dr. Burstein (which contradicts her affidavit at ¶ 4, in which she gives an onset of two to three weeks). That is almost five weeks.

In the Omnibus proceedings, respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days

to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at \*15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). The almost five weeks here exceeds that time period.

Petitioner must file an expert report stating that hepatitis B vaccine caused Brian's ADEM almost five weeks later by **September 29, 2006** or this case will be dismissed. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **September 29, 2006**.

**IT IS SO ORDERED.**

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DATE

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Laura D. Millman  
Special Master